

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

SIDNEY HILLMAN HEALTH CENTER,)	
OF ROCHESTER, TEAMSTERS HEALTH)	
SERVICES AND INSURANCE PLAN)	
LOCAL 404, and UNITED FOOD AND)	
COMMERCIAL WORKERS UNIONS AND)	
EMPLOYERS MIDWEST HEALTH)	No. 13 C 5865
BENEFIT FUND, on behalf of themselves and)	
all others similarly situated,)	Judge Sara L. Ellis
)	
Plaintiffs,)	
)	
v.)	
)	
ABBOTT LABORATORIES and)	
ABBVIE INC.,)	
)	
Defendants.)	

OPINION AND ORDER

Sidney Hillman Health Center of Rochester, Teamsters Health Services and Insurance Plan Local 404, and United Food and Commercial Workers Unions and Employers Midwest Health Benefit Fund (collectively, “the Funds”) are multi-employer benefit plans and health services funds that provide health benefits, including prescription drug coverage, to their members. The Funds seek to represent a nationwide class of such third-party purchasers or third-party payors (“TPPs”) who from 1998 to 2012 reimbursed and paid all or some of the purchase price for Depakote, a drug developed and marketed initially by Abbott Laboratories (“Abbott”) and later by AbbVie, Inc. (“AbbVie”) (collectively, “Abbott”), for indications not approved by the Food and Drug Administration (“FDA”).¹ Plaintiffs also seek to represent three subclasses of TPPs in Illinois, New York, and Massachusetts. The Funds bring claims for violations of the

¹ In 2012, Abbott Laboratories split into two separate companies, Abbott, focused on the development and sale of medical products, and AbbVie, focused on the development and sale of pharmaceuticals.

Racketeer Influenced and Corrupt Organizations Act (“RICO”), conspiracy to violate RICO, violation of the Illinois and New York deceptive business practices acts, and unjust enrichment. Abbott has moved to dismiss the Complaint. Because the Court finds the Funds’ RICO claims are barred by the statute of limitations, Abbott’s motion [26] is granted as to Counts I and II and the Court declines to exercise jurisdiction over the remaining state law claims (Counts III-VII).

BACKGROUND²

Depakote (divalproex sodium) was developed by Abbott and approved by the FDA for the treatment of epileptic seizures, acute mania or mixed episodes associated with bi-polar disorder, certain absence seizures, adult migraine prevention and prophylaxis, and pediatric patients over ten years old for certain absence seizures. Depakote has never been approved for treatment of dementia, including agitation associated with dementia, schizophrenia, ADHD, narcotic drug withdrawal, or any other uses.

Between 2007 and 2012, four sealed *qui tam* actions were filed against Abbott pursuant to the False Claims Act, 31 U.S.C. § 3730(b), asserting illegal marketing of Depakote for non-FDA approved uses. In November 2009, Abbott disclosed in a public Securities and Exchange Commission filing that the United States Department of Justice was investigating its sales and marketing of Depakote. This was widely reported in the press at that time.³ On February 1, 2011, the *qui tam* actions were unsealed as the United States and fifteen state governments

² The facts in the background section are taken from the Funds’ complaint and are presumed true for the purpose of resolving Abbott’s motion to dismiss. *See Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011). The Court may also take judicial notice of matters of public record without converting a Rule 12(b)(6) motion into a motion for summary judgment. *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080–81 (7th Cir. 1997).

³ The Court takes judicial notice of the fact of the publication of these articles. *See Garber v. Legg Mason, Inc.*, 347 F. App’x 665, 669 (2d Cir. 2009) (approving judicial notice of SEC filings and the fact of press coverage); *Lehman v. Vill. of Oak Park, Ill.*, 420 F. Supp. 2d 892, 895–96 (N.D. Ill. 2006) (taking judicial notice of fact of newspaper publication on motion to dismiss).

intervened. Another state followed two months later. After the consolidation of those actions, on May 7, 2012, Abbott agreed to pay \$1.6 billion to resolve the criminal and civil claims against it. As part of that settlement, Abbott admitted to knowingly promoting the sale and use of Depakote for uses that the FDA had not approved as safe and effective, including behavioral disturbances in dementia patients, ADHD, schizophrenia, and other psychiatric conditions. Abbott also admitted this unapproved use promotion included making false and misleading statements about the safety, efficacy, dosing, and cost-effectiveness of Depakote for some of those uses, and specifically marketing Depakote to nursing homes to control behavioral disturbances in dementia patients (as an alternative to antipsychotic medications that carried additional federal regulatory restrictions). Abbott also admitted to paying illegal remuneration to health care professionals and long-term pharmacy providers to induce them to promote or prescribe Depakote.

The Funds filed the current suit on August 16, 2013 alleging Abbott perpetrated a scheme designed to cause the Funds and other TPPs to pay for Depakote prescriptions to treat non-FDA approved conditions and conditions for which there is no reliable scientific evidence that Depakote is effective. The Funds claim their member-patients received no additional benefit from the drug (versus a placebo) and member-patients were sometimes subjected to additional side effects, despite alternative medicines that were cheaper, more effective, or had fewer side effects.

According to the Funds, Abbott perpetrated this scheme in direct violation of FDA regulations concerning the marketing and promotion of prescription drugs. The FDA requires pharmaceutical companies to present fair and balanced information about their products, meaning full disclosure of negative as well as positive information. Promotion of drugs for “off-

label,” or unapproved uses, is also closely monitored by the FDA. In limited circumstances and following FDA guidelines, drug companies can provide information on off-label uses of their products. For example, companies may respond to physicians who specifically inquire about off-label uses, discuss these off-label uses with *bona fide* consultants for the purpose of retaining their services for the pharmaceutical company, and provide grants to independent continuing medical education program sponsors (that may discuss these uses), provided the drug company does not influence the content of those programs. Off-label prescription of drugs is not illegal and is a routine practice among physicians.

According to the Complaint, from 1998 to 2012, Abbott used intermediary marketing firms, allegedly independent entities, and paid physician spokespeople to aggressively market Depakote for off-label uses. Abbott also used internal sales divisions to target physicians and institutions to increase off-label prescriptions. These efforts resulted in dramatically increased sales of Depakote, including to a high of \$1.5 billion by 2007.

The Funds allege Abbott established and controlled three enterprises to promote off-label uses of Depakote and to make misrepresentations about its safety and effectiveness for those uses. The “CENE Enterprise” was comprised of Abbott, associated physicians, and two other entities. One entity, the Council for Excellence in Neuroscience Education (“CENE”) was a purportedly independent continuing education medical group with undisclosed ties to Abbott. CENE disseminated webinars, meetings, and materials on off-label Depakote uses. CENE also had “faculty” and “council” physician members retained to promote Depakote for unapproved uses. The second entity, ACCESS Medical Group (“ACCESS”) was hired by Abbott to assist CENE by creating continuing education materials, including slide show presentations for use by doctors in Abbott’s speakers’ bureau. The “PharmaCare Enterprise” included Abbott, its sales

representatives, and PharmaCare Strategies, Inc. (“PharmaCare Strategies”), a market development firm that trained Abbott employees to successfully promote Depakote for off-label uses. The third enterprise, the “ABcomm Enterprise,” was designed to funnel kickbacks to physicians to drive prescription writing habits and increase off-label sales of Depakote. The ABcomm Enterprise included the physicians and other medical professionals, Abbott, and ABcomm, Inc. (“ABcomm”), a medical continuing education provider that created training materials and provided live activities. The Complaint alleges Abbott controlled and participated in each of these enterprises with the goal of increasing the amount of off-label Depakote prescriptions purchased by the TPPs. The Complaint also states the predicate RICO acts were bribery, along with mail and wire fraud associated with the communications with physicians to induce additional prescriptions.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the plaintiff’s complaint and draws all reasonable inferences from those facts in the plaintiff’s favor. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). To survive a Rule 12(b)(6) motion, the complaint must not only provide the defendant with fair notice of a claim’s basis but must also be facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

Rule 9(b) requires a party alleging fraud to “state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). This “ordinarily requires describing the ‘who, what, when, where, and how’ of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case.” *AnchorBank*, 649 F.3d at 615 (citation omitted). Rule 9(b) applies to “all averments of fraud, not claims of fraud.” *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007). “A claim that ‘sounds in fraud’—in other words, one that is premised upon a course of fraudulent conduct—can implicate Rule 9(b)’s heightened pleading requirements.” *Id.*

ANALYSIS

I. Statute of Limitations for the Funds’ RICO Claims (Counts I & II)

A. The RICO Limitations Period

Abbott has moved to dismiss the Funds’ Complaint on the basis that the RICO claims are barred by the statute of limitations and therefore fail to state a claim. Although a complaint need not anticipate an affirmative defense such as the statute of limitations to survive a motion to dismiss, “[a] litigant may plead itself out of court by alleging (and thus admitting) the ingredients of a defense.” *U.S. Gypsum Co. v. Indiana Gas Co.*, 350 F.3d 623, 626 (7th Cir. 2003).

The Supreme Court has set a four year statutory limitations period for civil RICO claims. *See Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156, 107 S. Ct. 2759, 97 L. Ed. 2d 121 (1987) (adopting four year limitations period for civil RICO but specifically declining to determine when the accrual period begins). The Court subsequently clarified that a plaintiff may bring suit within four years of discovery of his or her injury and rejected the rule that the statute begins to run when the plaintiff discovers both his injury and the pattern of alleged racketeering activity. *Rotella v. Wood*, 528 U.S. 549, 554, 120 S. Ct. 1075, 145 L. Ed. 2d

1047 (2000). Although the Supreme Court explicitly refused to settle on a final rule (and allowed for other possibilities, including an injury occurrence rule), *id.* at 554 n.2, the Seventh Circuit has subsequently approved the injury discovery rule. *See, e.g., Cancer Found., Inc. v. Cerberus Capital Mgmt.*, 559 F.3d 671, 674–75 (7th Cir. 2009).

The civil RICO clock begins to run “when the plaintiffs discover, or should, if diligent, have discovered, that they had been injured by the defendants.” *Id.* at 674. “There must, of course, be a pattern of racketeering before the plaintiff’s RICO claim accrues, and this requirement might delay accrual until after the plaintiff discovers her injury.” *McCool v. Strata Oil Co.*, 972 F.2d 1452, 1465 (7th Cir. 1992).⁴ The RICO plaintiffs need only have discovered the harm itself and do not need to know that the injury is actionable. *Cancer Found.*, 559 F.3d at 674. And although “[d]ismissing a complaint as untimely at the pleadings stage is an unusual step . . . dismissal is appropriate when the plaintiff pleads himself out of court by alleging facts sufficient to establish the complaint’s tardiness.” *Id.* at 674–75.

The Funds state they were injured by paying for their members’ Depakote prescriptions “to treat conditions for which the drug is not FDA approved and for which there was no reliable scientific evidence that Depakote was effective.” Compl. ¶¶ 204–205. The Funds further claim a class period of 1998 to 2012, during which time they “reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA.” *Id.* ¶¶ 211, 213–15. As pleaded, the first notice the Funds had of their alleged injury – the payment for prescriptions for off-label Depakote use – was in 1998 when they reimbursed the initial prescription. *See id.*

⁴ So while the pattern of racketeering acts is required for the cause of action, it is the plaintiff’s discovery of her injury from which the statute of limitations is determined. *See McCool*, 972 F.2d at 1465 (“[W]e, like the Supreme Court, have maintained that there is an important distinction between discovery of an *injury* and discovery of a *cause of action*. The pattern element of RICO gives rise to the cause of action, but is not the injury itself.”).

Therefore the statute of limitations began to run in 1998, over a decade before the August 16, 2009 RICO cut-off.

As rightly argued by Abbott, the Funds and other TPPs in charge of health benefit plans are sophisticated entities with a fiduciary duty to their beneficiaries to monitor the prescriptions for which they pay. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 195–96 (E.D.N.Y. 2008), *rev'd on other grounds sub nom. UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (describing TPPs as having “a continuing duty to their clients to inquire” into the drugs paid for, “an affirmative duty to be alert to dangers to clients,” and “expertise in merchandising of pharmaceuticals and fiduciary responsibilities to their clients”). It was in 1998, at the alleged first payments, that the Funds either did or should have discovered that they were reimbursing the cost of Depakote for off-label uses. *See Cancer Found.*, 559 F.3d at 674.

The Funds do not allege any other kind of injury or any change in the scheme from 1998 to 2012. Most importantly, the Funds do not plead any separate, predicate RICO act within the four years before the Complaint was filed that might qualify under the separate accrual doctrine. The separate accrual doctrine “applies to new events by the enterprise that lead to new injuries,” but a plaintiff “cannot use an independent, new act as a bootstrap to recover for injuries caused by other predicate acts that took place outside the limitations period.” *Zalesiak v. UnumProvident Corp.*, No. 06 C 4433, 2007 WL 4365345, at *6 (N.D. Ill. Dec. 12, 2007) (dismissing civil RICO claim as barred by the statute of limitations). The Funds’ response does not even address this issue and the Court can find no allegations to support the argument that a new act by Abbott or its alleged enterprises led to any new injuries after August 2009. The separate accrual doctrine is not available to salvage either of the Funds’ RICO claims.

B. Equitable Estoppel and Equitable Tolling

1. Equitable Estoppel

The Funds argue that equitable estoppel should apply to toll the statute of limitations. Equitable estoppel, or fraudulent concealment, suspends the running of the statute of limitations when “the defendant takes active steps to prevent the plaintiff from suing in time.” *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 450–51 (7th Cir. 1990). This requires efforts by the defendant – “above and beyond the wrongdoing upon which the plaintiff’s claim is founded” – that prevent the plaintiff from timely pursuing his or her claims. *Id.* at 451. “Fraudulent concealment . . . is distinct from a fraud that is concealed.” *Wolin v. Smith Barney Inc.*, 83 F.3d 847, 851 (7th Cir. 1996). Examples of the active steps by a defendant that may invoke equitable estoppel include the destruction of evidence, tampering with evidence, or an affirmative statement by the defendant that it would not assert a statute of limitations defense. *See id.* at 852; *Cancer Found.*, 559 F.3d at 676. The Supreme Court has determined a plaintiff must exercise “reasonable diligence” in discovering its claims. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 194–96, 117 S. Ct. 1984, 138 L. Ed. 2d 373 (1997).

Equitable estoppel does not apply here because the Funds do not plead any additional actions on the part of Abbott – beyond the concealment necessary for the success of the marketing scheme – that were active steps designed to prevent the Funds from timely filing suit. *See* Compl. ¶¶ 199–202. For example, the Complaint alleges the “off-label marketing scheme depended on Abbott’s concealment of its involvement in the off-label promotion of Depakote,” that Abbott worked through the seemingly independent third-party enterprises, and that Abbott hid its financial connections to physicians who promoted Depakote for off-label purposes through those enterprises. *Id.* ¶¶ 199–201. Modifications to the CENE website, including the

elimination of the website entirely, are pleaded in the Complaint as part of the CENE Enterprise and RICO claims. *See* Compl. ¶¶ 103–05, 129. Nowhere does the Complaint assert that the concealment of Abbott’s ties to CENE was designed to prevent any plaintiffs from bringing suit. Rather these actions as pleaded were designed to ensure the success of Abbott’s off-label marketing and to evade detection by the FDA. *See, e.g., id.* ¶ 199 (“The off-label marketing scheme *depended on* Abbott’s concealment of its involvement in the off-label promotion of Depakote.” (emphasis added)). The Funds’ bald assertion of Abbott’s concealment does not require the Court to invoke this equitable doctrine, which is available only under limited circumstances. *See Smith v. City of Chicago Heights*, 951 F.2d 834, 840–41 (7th Cir. 1992).

2. Equitable Tolling

Equitable tolling differs from equitable estoppel in that the plaintiff must show he or she could not “by the exercise of reasonable diligence have discovered essential information bearing on his [or her] claim,” but does not need to allege that the defendant acted in any way to obscure the potential claim. *Cada*, 920 F.2d at 451–52. “[T]he plaintiff must be continuously diligent and sue (if he is beyond the statutory period) as soon as it is practicable for him to do so.” *Wolin*, 83 F.3d at 853. Even with due diligence, a claim may not be equitably tolled for an indefinite period of time. As the Seventh Circuit explained, “a plaintiff who invokes equitable tolling to suspend the statute of limitations must bring suit within a reasonable time after he has obtained, or by due diligence could have obtained, the necessary information.” *Cada*, 902 F.2d at 453. That window is relatively brief. *See id.* at 453 (finding a delay of eight months too long); *Elmore v. Henderson*, 227 F.3d 1009, 1013 (7th Cir. 2002) (four months’ delay too long); *Hentosh v. Finch Univ. of Health Sci./Chicago Med. Sch.*, 167 F.3d 1170, 1175 (7th Cir. 1999)

(nearly seven months' delay too long); *Thelen v. Marc's Big Boy Corp.*, 64 F.3d 264, 268 (7th Cir. 1995) (nearly ten months' delay too long).

The Funds argue their discovery of the RICO claim, rather than the initial injury of paying for off-label Depakote prescriptions, should trigger this doctrine. However, the cited cases do not support the idea that equitable tolling begins when the plaintiff becomes aware of the racketeering claim rather than the direct injury. Rather, "[i]n the context of RICO, . . . equitable tolling may delay the running of the limitations period while a victim diligently investigates the possible existence and extent of a pattern of racketeering." *See Jones v. Burge*, No. 11-cv-4143, 2012 WL 2192272, at *4 (N.D. Ill. June 13, 2012) (citation omitted) (internal quotation marks omitted). This gives injured plaintiffs some leeway to investigate the extent of a potential enterprise after detecting their injury, but does not shift the limitations inquiry to discovery of the RICO acts. *See Bontkowski v. First Nat'l Bank of Cicero*, 998 F.2d 459, 462 & n.4 (7th Cir. 1993) (finding no tolling, analyzing plaintiff's knowledge of his own direct injury). Key to equitable tolling is the plaintiff's diligent inquiry and the Funds cannot point to any allegations in the Complaint that would support a finding that they conducted any investigation whatsoever, much less any diligent attempts to obtain information about their alleged injury.

As discussed above, the Funds' claimed injury is the payment for ineffective off-label prescriptions of Depakote. The Funds allege they began paying for these prescriptions in 1998 and it was at that point that the Funds could or should have discovered they were paying for off-label uses. A reasonable plaintiff would have discovered its injury in 1998 and would have to allege some attempt to investigate at that point to trigger any consideration of equitable tolling. And even if the proper inquiry for RICO equitable tolling was discovery of the RICO claim, by 2009, when the SEC filing notified the public that Abbott's marketing for Depakote was under

investigation and prompted extensive newspaper coverage, a reasonable TPP would have such notice of a potential claim. Or, even if the Funds were not aware of either their injury or the RICO claim until the public May 2012 settlement as they argue, a fifteen month delay in filing suit is too long to consider equitable tolling under the case law in this circuit. *See Cada*, 902 F.2d at 453; *Elmore*, 227 F.3d at 1013; *Hentosh*, 167 F.3d at 1175; *Thelen*, 64 F.3d at 268. The Funds' broad statement that Abbott concealed its involvement in the marketing of Depakote is not enough to excuse their lack of diligence. *See Zalesiak*, 2007 WL 4365345, at *7 (finding plaintiff's statement that the defendant concealed their fraud inadequate to support tolling). There is no basis to apply this equitable doctrine here.

II. The Funds' Claims Under State Law and for Unjust Enrichment (Counts III-VII)

The Complaint also asserts claims under the Illinois Consumer Fraud and Deceptive Business Practices Act (815 Ill. Comp. Stat. 505/2), New York General Business Law Section 349, and for unjust enrichment on behalf of the Illinois, New York, and Massachusetts subclasses. The Court has dismissed the federal claims and therefore relinquishes pendent jurisdiction over these state law claims. *See United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 726-27, 86 S. Ct. 1130, 16 L. Ed. 2d 218 (1966).

CONCLUSION

For the foregoing reasons, Abbott's motion to dismiss [26] is granted. Counts I and II are dismissed with prejudice. Counts III-VII are dismissed without prejudice to refiling in state court.

Dated: May 12, 2014



SARA L. ELLIS
United States District Judge